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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,295	03/12/2004	Michael P. Wallace	30-7038152001 04-050 (USO)	8148
7590	09/19/2005			EXAMINER AGUEL, FERNANDO
Bingham McCuthen, LLP Suite 1800 Three Embarcadero San Francisco, CA 94111-4067			ART UNIT 3762	PAPER NUMBER

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/799,295	WALLACE ET AL.
	Examiner	Art Unit
	Fernando Aguel	3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 12 March 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-27 is/are pending in the application.
 - 4a) Of the above claim(s) 1-15 and 25-27 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 16-24 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/24/04 & 3/25/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Claims 1 – 15 and 25 – 27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected medical lead assembly and processes of use, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8/24/05.

Information Disclosure Statement

2. The information disclosure statements (IDS) submitted on 3/25/04 and 9/24/04 are noted. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the information disclosure statements are being considered by the examiner.

Specification

3. The disclosure is objected to because of the following informalities: the headings in the specifications should not be underlined or in bold faced lettering.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 16 and 20 - 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischell et al (4141365). Fischell et al disclose an electrode bearing (column 1, lines

49 – 52) tubular lead made of flexible material (column 2, lines 9 – 12) having a rectangular or oval cross section (column 2, lines 18 – 22) in a flattened configuration (column 2, lines 18 – 22) inherently capable of being collapsed because the lead is made from a flexible material and is already in a “flattened” configuration, and is intended for epidural placement (column 2, lines 22 – 25) in the patient.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 17, 18, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al (4141365) in view of Hull et al (5417719). Fischell et al disclose the invention substantially as claimed but do not disclose that the tubular structure comprises a discrete resilient spring member nor a resilient mesh, nor do

Fischell et al disclose a crescent shaped lead. Hull et al teach a lead paddle comprising a spring in the form of a mesh made of a known resilient material (column 6, lines 48 – 52), also teach a crescent shaped (Figure 4, element 16) cross section for the lead. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Fischell et al by including a spring in the form of a resilient mesh into the lead to prevent the lead from kinking and to allow the lead to regain it's original shape after implantation and to make the lead in a crescent shapes cross section to provide for better contact with the intended tissue.

9. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al (4141365) in view of Alt et al (6370427). Fischell et al disclose the invention substantially as claimed but do not disclose that the tubular member inhibits tissue growth. Alt et al teach a lead with a surface coating to inhibit tissue growth (column 12, lines 40 – 47). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Fischell et al by including a tissue growth inhibiting coating on the lead in order to prevent tissue from adhering to the lead and therefore restricting it's movement.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- a. Iverson (5902236)
- b. Erickson et al (6895283)

c. Kohnen et al (6249707)

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fernando Aguel whose telephone number is 571-272-8687. The examiner can normally be reached on M-F, 8:30-5:00.
12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FA

Fernando Aguel
9/6/05

GEORGE R. EVANISKO
PRIMARY EXAMINER

9/6/05